DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

Claims 79-96 are examined on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 11, 2008 has been entered.

Claim Rejections - 35 USC § 112

(New Rejection Necessitated by Amendments) Claims 79 and 81-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to a method for inducing an immune response against an influenza virus, comprising administering to a subject an effective amount of a vaccine formulation comprising a genetically engineered attenuated influenza virus and a physiologically acceptable excipient, in which the genome of the genetically engineered

attenuated influenza virus encodes a truncated NS 1 protein **composed of amino acid residues 1 to 99 of the NS 1 protein** of the same or a different influenza virus strain, so that the genetically engineered attenuated influenza virus has an impaired interferon antagonist phenotype

Actual reduction to practice: Applicants have successfully generated a reassortant influenza virus with an impaired interferon antagonist phenotype by truncating Non-Structural protein 1 (NS1) to only contain the first 99 amino acids. Applicants also state in the specification that in particular, the truncated NSI proteins have from 1-60 amino acids, 1-70 amino acids, 1-80 amino acids, 1-90 amino acids (the N-terminal amino acid is 1), and preferably 90 amino acids; from 1-100 amino acids, and preferably 99 amino acids; from 1-110 amino acids; from 1-120 amino acids; or from 1-130 amino acids, and preferably 124 amino acids of the wild-type NSI gene product (see page 18).

Method of making the claimed invention: Applicants have disclosed on pages 37-39 a method of generating the reassortant virus with the specific mutation of amino acids 1-99 of the NS1 protein included in the virus.

Level of skill and knowledge in the art: One skilled in the art of molecular virology could readily construct a reassortant influenza virus with a mutated NS1 protein that lacks some portion of the C-terminus region.

Predictability in the art: The art of generating an impaired interferon antagonist phenotypic influenza virus, in which the virus has a C-terminus truncated NS1 protein is acknowledged to be unpredictable. For example, truncation at positions 125 and 126 did not impair the ability of NS1 to down regulate IFN expression as presented by Ferko et

al. (Journal of Virology, 2004) see page 13041 and Wang et al. (Journal of Virology, 2002), see pages see page 12953.

Therefore, based on the breadth of the claimed invention and the reduction to practice of only one example of such a mutant virus and its impaired IFN antagonistic phenotype along with the state of the art recognizing that similar truncations do not result in such a phenotype, the applicants are not in possession of the claimed invention.

(New Rejection Necessitated by Amendments) Claims 80 and 85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is drawn to a method of inducing an immune response to an influenza virus by administering the influenza strain NS1/99. However, the claimed invention requires what appears to be a specific strain of influenza virus. If in fact, the claimed virus is not a specific strain, but any influenza virus that contains a truncated NS1 protein with only the first 99 amino acids present, perhaps amending the above claims to recite such a limitation, could clarify that it is not a specific strain.

It is apparent that influenza strain NS1/99 is required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the influenza NS1/99 strain. See 37 CFR 1.802. Access to the influenza NS1/99 strain is required to practice the invention. The specification does not provide a repeatable method for administering

the NS1/99 strain to a host without access to the influenza NS1/99 strain and it does not appear to be readily available material.

Deposit of the influenza NS1/99 strain in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:
(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648